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09/732,091	12/07/2000	Jing-Hui Tian	7969-088-999	3097

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/732,091	Applicant(s) Tian et al
	Examiner Portner	Art Unit 1645

-- ***The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 7, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-78* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-78 are pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7,8-10,15-24,25-29,41,57-59; methods 42-44, 60-62,67, 68, 69 are , to a plurality of independent and distinct species, drawn to an isolated and purified *polypeptide* of **30 kDa**, fragments, combination fusion polypeptides of various portions of the 30 kDa polypeptide, as well as a plurality of independent and distinct methods of administering a **30** kDa polypeptide to an animal, classified in class 424, subclass 185.1.

II. Claims 1-7,8-10,15-24,25-29,41,57-59; methods 42-44, 60-62,67, 68, 69 are, drawn to a plurality of species directed to isolated and purified *polypeptide* of **56 kDa**, fragments, combination fusion polypeptides of various portions of the 56 kDa polypeptide; as well as drawn to a plurality of independent and distinct methods of administering a **56** kDa polypeptide to an animal , classified in class 424 subclass 190.1 .

III. Claims 8-10, 15-24, 31-32, 41; methods claims 47, 62, 64-65, 67, 68-69, 70-71, 76-78 drawn to a plurality of species defined by a **combination of a 30kDa and 56 kDa** *polypeptide*, or the 30 kDa and/or 56 kDa polypeptide together with an additional antigen/immunogen that induces an immune response, as well as a plurality of independent and distinct methods of administering a composition that comprises a fusion polypeptide that is a combination of a portion of a 30 kDa polypeptide together with a portion of a **56** kDa polypeptide to an animal, and/or optionally an additional

immunogen and one or more antibiotics , classified in class 435, subclass 69.7 .

IV. Claims 11-14, 30; method claim 63,69-71 drawn to *antibody* immunoreactive with a **30 kDa** polypeptide, fragments, combination fusion polypeptides of various portions of the 30 kDa polypeptide, as well as a plurality of methods of administering *an antibody* to a **30** kDa polypeptide to an animal , classified in class 530, subclass 387.1.

V. Claims 11-14, 30; methods 63, 69-71 are, drawn to *antibody* immunoreactive with a **56 kDa** polypeptide, fragments, combination fusion polypeptides of various portions of the 56 kDa polypeptide, drawn to a plurality of methods of administering *an antibody* to a **56** kDa polypeptide to an animal , classified in class 530, subclass 387.9.

VI. Claims 33-41, 48, 50-56; methods claims 45-46, 66-67, 69-71 are, drawn to a plurality of species of *nucleic acid* that encode a **30 kDa** polypeptide, fragments, and regions of the polypeptide, vectors, host cells that comprise the nucleic acid; as well as a plurality of methods of administering a nucleic acid that encodes a **30** kDa polypeptide, or specific portions thereof to an animal , classified in class 536, subclass 23.1.

VII. Claims 33-41, 49-56; methods claims 45-46, 66-67, 69-71 are , drawn to ,drawn to a plurality of species of *nucleic acid* that encode a **56 kDa** polypeptide, fragments, and regions of the polypeptide, vectors, host cells that comprise the nucleic acid, as well as a plurality of methods of administering a **nucleic acid that encodes** a **56** kDa polypeptide to an animal , classified in class 536, subclass 23.7.

VIII. Claim 41,methods: 67, 69-71 are ,drawn to a plurality of species of *nucleic acid* vaccine combination compositions that encode both a **30 kDa and 56 kDa** polypeptide, fragments, and regions of the polypeptide, as well as vectors, host cells that comprise the nucleic acid, a method that comprises the step of administering the combination composition to an animal classified in class 536, subclass 23.4.

IX. Claims 47,69-71 drawn to a plurality of methods of administering a combination of immunogens that includes *a combination of a polypeptide together with a nucleic acid* to an animal , classified in class 424, subclass 282.1 .

X. Claims 47,69-71 drawn to a plurality of methods of administering a combination of immunogens that includes *a combination of a polypeptide together with an antibody* to an animal , classified in class 424, subclass 178.1 .

XI. Claims 47, 69-71 drawn to a plurality of methods of administering a combination of immunogens that includes *a combination of nucleic and an antibody to an animal* to an animal , classified in class 514, subclass 44 .

XII. Claim 72, drawn to an antagonist of a 30 kDa polypeptide, classified in class 424, subclass 164.1.

XIII. Claim 72, drawn to an antagonist of a 56 kDa polypeptide, classified in class 530, subclass 387.9.

XIV. Claim 73, drawn to drawn to an antagonist of a nucleic acid that encodes 30 kDa polypeptide, classified in Class 536, subclass 24.5.

XV. Claim 73 ,drawn to drawn to an antagonist of a nucleic acid that encodes 56 kDa polypeptide, classified in Class 536, subclass 24.5.

XVI. Claim 74, drawn to drawn to a method of identifying compounds that interact with a 30 kDa polypeptide, classified in class 435, subclass 7.1 .

XVII. Claim 74, drawn to drawn to a method of identifying compounds that interact with a 56 kDa polypeptide, classified in class 435, subclass 7.32.

XVIII. Claim 75, drawn to a method of identifying compounds that interact with a nucleic acid that encodes a 30 kDa polypeptide, classified in class 435, subclass 6.

XIX. Claim 75, drawn to drawn to a method of identifying compounds that interact with a nucleic acid that encodes a 56 kDa polypeptide, classified in Class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

3. The invention of group I or II or III is distinct from the invention of group VI, VII or VIII, respectively because the inventions are drawn to materially different compositions that require non-coextensive areas of search and consideration. For example, the polypeptides of the invention of Group I, or II, or III may be isolated from natural sources, or synthesized synthetically and are not necessarily defined by the DNAs that encode them.

4. Inventions Group I and Group II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group I has separate utility such as in a method of identifying antagonists specific for the 30 kDa polypeptide, detecting antibodies specific to the 30 kDa polypeptide, while the 56 kDa

polypeptide can be used to detect antagonists to the 56 kDa polypeptide that do not bind or interact with the 30 kDa polypeptide. See MPEP § 806.05(d).

5. Inventions Group I or II and Group III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions of Group I or II has separate utility such as in a method of identifying antagonists specific for the 30 kDa polypeptide, detecting antibodies specific to the 30 kDa polypeptide, 56 kDa polypeptide can be used to detect antagonists to the 56 kDa polypeptide that do not bind or interact with the 30 kDa polypeptide, and the fusion polypeptide of Group III can be used to induce an immune response to two polypeptides rather than just one. See MPEP § 806.05(d).

6.The inventions of groups I (30kda) or II (56kda) are distinct from the binding molecules and antagonists of groups IV or XII (30 kDa) , and Groups V or XIII (56 kDa) , because they are drawn to materially different polypeptides with distinct structural and chemical properties. Specifically, the binding compounds of groups IV or XII (30 kDa) , and Groups V or XIII (56 Kda) which encompasses antibodies, as well as other compounds, requires search and consideration of the preparation of the polypeptide binding agent/ antagonist and at a structural level, antibodies are disparate from the proteins that they may bind.

7. Inventions groups (IV or V) and (XII or XIII) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions of Groups IV or V have separate utility in methods of purifying a polypeptide, in methods of detecting infection, as well as in methods of treating infection, while the antagonists of Groups XII or XVIII, which include molecules that only function as antagonists of the recited polypeptides, but have not been defined as diagnostic agents. See MPEP § 806.05(d).

8. Inventions Groups III, VIII, IX, X, XI and are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group III can be used in a method of detecting antibodies associated with infection. Groups III, VIII, IX, X and XI are directed to the administration of compositions that structurally and functionally differ one from the other, wherein a nucleic acid (VIII, IX and XI), an antibody (see Group X and XI) and a polypeptide (Groups III, IX, X) all evidence different, separate modes of action, differ in structure, function and biological effect and evidence different utilities such as transformation of a host cell for expression of the encoded polypeptide over a long period of time (nucleic acid), the antibody can immediately bind to the polypeptide for providing protection, as well as can be used to produce anti-idiotype antibodies to mimic bacterial antigen (antibody), and the polypeptide can be used to induce an immune response without first transforming a host cell, as well as be used in a method of diagnosis of infection . See MPEP § 806.05(d).

9. Inventions I or II and XVI or XVII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product , specifically in methods of purifying antibodies, as well as in methods of treating infection .

10. Inventions of Groups XV or XVI, and Groups XVII or XVIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product , specifically in

methods of treating infection, and in the case of an antibody antagonist, in methods of purifying proteins and in methods of detecting proteins associated with infection.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. This application contains claims directed to the following patentably distinct species of the claimed invention:

13.Claims in Groups I-III, VIII, IX, X and XI are directed to a plurality of disclosed patentably distinct species of product comprising materially different compositions. Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product within a single group , even though this requirement is traversed. The separate products which bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Group I species:

30 kDa;

fragments of 30 kDa of at least 6 amino acids of SEQ ID NO 4;

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 16-20;

Group II species:

56 kDa;

fragments of 56 kDa of at least 6 amino acids of SEQ ID NO 2;

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 5-15;

Group III:

14. Select one portion from the 30 kDa polypeptide:

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 16-20;

Select one portion from the 56 kDa polypeptide:

fragments of 56 kDa of at least 6 amino acids of SEQ ID NO 2;

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 5-15;

15. Or Select one of the additional species:

a.30kDa plus 56 kDa, plus an additional immunogen

b.30kDa plus 56 kDa, plus an additional immunogen and an adjuvant

c.30kDa plus 56 kDa, plus an additional immunogen, a carrier or diluent and an antibiotic.

d.30kDa plus 56 kDa, plus an additional immunogen, a carrier or diluent and an antibiotic, and an adjuvant.

Group VIII: Nucleic acid vaccine that encodes the:

e.30kDa plus 56 kDa, plus an additional immunogen

f.30kDa plus 56 kDa, plus an additional immunogen and an adjuvant

g.30kDa plus 56 kDa, plus an additional immunogen, a carrier or diluent and an antibiotic.

h.30kDa plus 56 kDa, plus an additional immunogen, a carrier or diluent and an antibiotic, and an adjuvant.

Group IX: Combination vaccine of a polypeptide and a nucleic acid, wherein:
Select one polypeptide species to be combined with a nucleic acid) is :

30kDa

56 kDa

peptide fragment(s) of 30 kDa

peptide fragment(s) of 56 kDa, plus an additional immunogen

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 5-15;

Select one Nucleic acid species to be combined with the polypeptide:

i. A species recited in claim 33 (either 30 kda fragment or 56 kDa fragment)

j. A nucleic acid species recited in claim 41 together with an adjuvant;

k. A nucleic acid recited in (claim 36 depends from claim 33) claim 33 together with an additional immunogen;

l. A nucleic acid recited in claim 41 together an adjuvant and an additionally recited immunogen.

m. A nucleic acid recited in claim 41 together an adjuvant and an additionally recited immunogen and an antibiotic.

Group X. Combination vaccine of a polypeptide and an antibody, wherein:

Select one polypeptide species to be combined with an antibody is :

30kDa

56 kDa

peptide fragment(s) of 30 kDa

peptide fragment(s) of 56 kDa, plus an additional immunogen

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 16-20;

fusion protein of two SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of three SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of four SEQ ID Nos selected from SEQ ID Nos 5-15;

fusion protein of five SEQ ID Nos selected from SEQ ID Nos 5-15;

Select one antibody to be combined with the polypeptide:

n. An antibody immunoreactive with the 30 kda polypeptide; or

o. An antibody immunoreactive with the 56 kDa polypeptide.

Group XI:

Select one Nucleic acid species to be combined with an antibody:

p. A species recited in claim 33 (either 30 kda fragment or 56 kDa fragment)

q. A nucleic acid species recited in claim 41 together with an adjuvant;

r. A nucleic acid recited in (claim 36 depends from claim 33) claim 33 together with an additional immunogen;

s. A nucleic acid recited in claim 41 together an adjuvant and an additionally recited immunogen.

t. A nucleic acid recited in claim 41 together an adjuvant and an additionally recited immunogen and an antibiotic.

Select one antibody to be combined with the polypeptide:

u. An antibody immunoreactive with the 30 kda polypeptide; or

v. An antibody immunoreactive with the 56 kDa polypeptide.

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

17. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

VGP September 30, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600